

Introduction

Compliance with these terms and conditions and guidance and any future guidance, rules, regulations, terms and conditions, or laws is required of licensees to remain eligible and in good standing with the Adult-Use Conditional Processor license program. Applicants who are not compliant with these terms and conditions and guidance or any future guidance, rules, regulations, terms and conditions, or laws risk losing their conditional license and jeopardize their ability to secure a future Adult-Use Processor or other Adult-Use cannabis license. The Adult-Use Conditional Processor License is valid for up to two years from the date of issuance of the license. All Adult-Use Conditional Processor licenses become invalid after June 30, 2024.

Adult-Use Conditional Processor Key Reporting Deadlines:

- Before beginning operations, all applicants must:

- Submit a complete Adult-Use Conditional Processor application with the required nonrefundable application and licensing fee and a signed copy of the terms and conditions page at the end of this guidance document.
- Schedule an inspection with the Office to inspect the licensed facility and verify compliance with Good Manufacturing Practices and this guidance.
- o If the applicant or licensee is requesting to perform hydrocarbon extraction activities, including using volatile solvents such as propane and butane, the applicant must submit required materials and documentation on the application and provide a letter or equivalent document as determined by the Office from the jurisdiction's fire marshal, local building code authority, or its equivalent, stating that the facility is approved to conduct the proposed activities and that the processor has demonstrated compliance with all applicable fire codes and/or regulations.

Ongoing Reporting Responsibilities.

- o Licensees must maintain a current list of processing activities and a list of any cannabis extracts or cannabis products to be produced at the facility. If a licensee is permitted to conduct extraction activities and requests to change such activities from what was provided on the application, the licensee must receive prior written approval from the Office. Notification of changes to extraction activities must be made no less than 30 days before commencement of planned activities.
- o If the licensee is requesting to perform hydrocarbon extraction activities, including using volatile solvents such as propane and butane, the licensee must submit a letter or equivalent document as determined by the Office from the jurisdiction's fire marshal, local building code authority, or its equivalent, stating that the facility is approved to conduct the proposed activities and that the processor has demonstrated compliance with all applicable fire codes and/or regulations, upon any request to change the proposed extraction method.
- Office. Ongoing resources tracking obligations will be outlined in adult-use regulations.



- Licensee who packages cannabis products for retail sale shall annually report through a method authorized by the Board, beginning one year after the date of licensure: the total amount of packaging material, by weight, sold, offered for sale, or distributed into the state by the licensee in the prior calendar year; the percentage of all packaging material sold, offered for sale, or distributed for sale in the state; and the total costs of packaging material.
- Upon the expiration of the Adult-Use Conditional Processor Program:
 - Licensees must submit, upon request, any records mandated herein, which will be used to evaluate
 whether the conditional licensee is eligible to transition to a full Adult-Use Processor license,
 pursuant to all applicable laws, regulations, and program guidance.

Definitions

- 1. Attractive to individuals under twenty-one means labeling, packaging, advertising and marketing that is pleasing or appealing to persons under the age of twenty-one by using or including, among other things: Cartoons; Bubble-type or other cartoon-like font; bright colors that are "neon" in appearance; similarities to products or words that refer to products that are commonly associated with or marketed in a manner so as to be attractive to individuals under twenty-one, including but not limited to, any imitation of food, candy, soda, drinks, cookies, or cereal, in labeling, packaging, advertising, or marketing; terms "candy" or "candies" or variants in spelling such as "kandy" or "kandeez"; symbols, images, characters, public figures, phrases, toys, or games that are commonly used to market products to individuals under the age of twenty-one; or images of individuals who could reasonably appear to be under the age of twenty-one.
- 2. *Edible* means food or beverage products that have been infused with cannabis extracts.
- **3.** *Extraction or Extracting* means the process of concentrating or isolating one or more phytocannabinoids from cannabis.
- **4.** *Good Manufacturing Practices (GMP)* means a quality control system for ensuring that products are consistently produced and controlled in accordance with current federal regulations 21 CFR Parts 111 or 117 established by the Food and Drug Administration (FDA).
- **5.** *Hazard Analysis Critical Control Point (HACCP)* means a systematic approach that identifies, evaluates and controls hazards significant to product safety.
- **6.** *Inventory Tracking System* means a system that is capable of tracking cannabis or cannabis product inventory. Licensees are required to maintain an inventory tracking system for all cannabis and cannabis products at their facility.



- **7.** Lot unique identifier means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of production, manufacturing, testing, holding, distribution, or recall of a lot of adult-use cannabis product can be determined.
- **8.** *Phytocannabinoid* means any of the chemical compounds, excluding terpenes or any other compounds that are the active principles of cannabis sativa, including but not limited to tetrahydrocannabinol (THC) and cannabidiol (CBD), and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section thirty-three hundred six of the public health law.
- 9. *Pre-roll* means cannabis that has been prepared in consumer-ready form for smoking.
- **10.** *Product Quality Plan* means a product specific risk-based assessment of product safety hazards, and the preventive measures identified to prevent or mitigate each hazard.
- **11.** *Representative Sample* means a sample of cannabis product of the same size and composition that is required for cannabis product testing by a cannabis laboratory that represents a unique lot of cannabis product processed. The representative sample(s) must be stored on-site at the licensee facilities and can be used as a replacement laboratory testing sample in the event the first sample is compromised, or the results of the analysis require that the lot be re-tested.
- 12. Sterile means free from bacteria or other living organisms, or totally clean.
- **13.** *Tincture* means a liquid cannabis product usually made with alcohol or glycerin that is often dosed with a dropper. Tinctures can be flavored and are usually placed under the tongue, where they are absorbed quickly.
- **14.** *Topical* means a type of cannabis product that is applied to the skin.
- **15.** *Total THC* means the sum of the percentage by weight or volume measurement of tetrahydrocannabinolic acid multiplied by 0.877, plus, the percentage by weight or volume measurement of THC.



Adult-Use Conditional Processing Guidance

- 1. Data Collection and Retention. Adult-Use Conditional Processor license holders are required to submit any records mandated herein to the Office upon request and in advance of transitioning to an Adult-Use Processor license. Compliance with practices outlined in this document will be considered in making licensing decisions.
- 2. General Record Keeping Requirements. A licensee must keep and maintain records required by this section for at least five years from the date of creation unless the Board requires the licensee to maintain records for a longer timeframe. Records must be legible and accurate and stored in a secured area protected from debris, moisture, contamination, hazardous waste, and theft. Intentionally misrepresenting or falsifying records may lead to penalties imposed by the Board, including but not limited to, suspension, cancellation or revocation of the Adult-Use Conditional Processor license, disqualification from future licensing opportunities, and fines.

Licensees shall make its premises and all books, systems, and records readily retrievable and available upon request.

Records must account for all activities of the licensee, including but not limited to:

- architectural diagrams and floorplans of the licensed premises, including designation of functional areas and square footage available;
- for new construction and major renovation of a facility, certification by an NYS-licensed architect or engineer that the facility complies with the 2020 NYS Stretch Energy Code, or most recent version;
- annual benchmarking of energy and water usage, with the first report to be completed no later than one year after the date of licensure;
- a sustainable packaging plan as detailed in this guidance and annual reporting on the following, to begin one year after date of licensure: the total amount of packaging material, by weight, sold, offered for sale, or distributed into the state by the licensee in the prior calendar year; the percentage of all packaging material sold, offered for sale, or distributed for sale in the state through internet transactions; and the total costs of packaging materials;
- plans for the handling, storage, and disposal of waste, including plans for organic waste and for any hazardous waste;
- financial records in accordance with generally accepted accounting principles, including, but not limited to, ownership information of all individuals directly or indirectly involved with the license, capitalization tables, organizational charts, investment and financial agreements with any party, bank statements, sales invoices, receipts, and any other records maintained for tax purposes;
- personnel records, including each employee's full name, Social Security number or individual taxpayer identification number, date of employment, date of termination of employment (if applicable) background check and disciplinary actions (if applicable);
- training records including the content of the training provided and the names of employees trained;
- any contracts or agreements regarding the licensed cannabis activity including but not limited to real estate arrangements, financial loans, vendors or distributors;
- all records related to advertising and marketing required by the Board or Office;
- standard operating procedures, including a product quality plan;



- laboratory testing results for each lot or batch of cannabis or cannabis product produced;
- code of ethics:
- policies and procedures that notify persons with disabilities of their rights under applicable federal
 and state laws and regulations and includes provisions prohibiting discrimination and providing
 reasonable accommodations;
- policies and procedures demonstrating promotion of diversity in the workplace;
- all other documents prepared or executed by or for the licensee in connection with the license.
- any other records required by the Cannabis Law or as determined by the Board or Office.

The failure of the licensee to comply with the requirements set forth in this section may result in enforcement action, including but not limited to monetary fines and penalties, and license suspension or revocation.

- **3. Operating Plan**. Processors must document, implement, and maintain an Operating Plan, which shall be made readily available to the Board or Office upon request, and that must include, at a minimum:
 - A site plan indicating the activities performed in each area and detailing all physical boundaries, further outlined in Section 4.
 - A security and employee training and safety plan that includes risk mitigation and accident prevention plans resulting from a risk assessment of all licensed activities.
 - A product quality plan for each cannabis product produced by the licensee that addresses the risks and hazards associated with the premises and the processing process.
 - A cannabis product sampling, analysis, and testing plan based on risks associated with materials or organisms normally present during the production of cannabis products and in accordance with any guidance or regulations issued.
 - A quality assurance plan that establishes criteria to detect, identity, prevent and track cannabis contamination, mislabeling, and mispackaging incidents.
 - A cannabis and cannabis product recall plan that includes an annual mock recall test.
 - A sustainable energy-use and conservation plan that addresses the sourcing and use of energy and sets energy efficiency goals including energy tracking policies, timelines and benchmarks.
 - A Sustainable Packaging Program as outlined in this guidance.
- **4. Site Plan.** A licensee shall document, implement, and maintain a site plan, which must be submitted upon request to the Office consisting of the following information:
 - architectural diagrams and floorplans of the licensed premises;
 - activities performed in each area of the licensed premises including the identification of equipment used in the processing process;
 - details of all parcel boundaries including but not limited to physical boundaries, roads, and water crossings of the property;
 - sanitary facilities, as applicable;
 - perimeter dimensions;
 - entrances and exits to both the property and premises;



- a processor shall also include in its site plan the following additional information:
 - bulk packaging area;
 - composting area, if on-site;
 - cannabis waste area (not including composting areas); and
 - any other information as determined by the Office.
- **5.** Environmental, Energy Efficiency, and Conservation. A licensee shall engage with energy efficiency programs as determined by the Board and must participate in an environmental sustainability program.
- **6. Good Manufacturing Practices.** All cannabis processing shall be in accordance with Good Manufacturing Practices (GMP) standards, pursuant to either Part 111 or Part 117 of Title 21 of the Code of Federal Regulations, as applicable for the type of product being manufactured or as otherwise determined by regulation and/or the Board. Licensees must demonstrate compliance with GMP by submitting in their application to the Office, proof of a qualified third-party GMP audit of the processor's extraction and/or manufacturing facility operations and any related certification or audit report. Licensees are required to maintain proof of a current GMP qualified third-party audit for the duration of the license and make evidence of such audit readily available to the Office upon request.
- **7. General Sanitary Practices.** A processor must maintain all designated processing areas in accordance with general sanitary practices which are included in Good Manufacturing Practices as set forth in Part 111 or Part 117 of Title 21 of the Code of Federal Regulations. The licensee is responsible for the upkeep and maintenance of all facilities, containers, tools, contact surfaces, and equipment used in the processing, packaging, labeling, distribution, transportation, storage and sale of cannabis and cannabis products. All processors must:
 - have floors, walls and ceilings constructed in such a manner that they may be adequately kept clean and in good repair;
 - utilize containers, tools, contact surfaces, and equipment that are designed and of such material and workmanship as to be adequately cleanable and designed, maintained, operated and arranged as to protect against the physical, chemical, and microbial contamination and deterioration of the cannabis and cannabis products;
 - use containers that are food-grade, or of a similar standard as approved by the Office, for the storage of cannabis and cannabis products. Containers shall be clean, in good repair and suitable for the established use:
 - maintain all facilities, areas, containers, tools, contact surfaces, and equipment, in a clean and sanitary condition. Cleaning and sanitizing shall be as frequently as necessary to protect against contamination, using a sanitizing agent registered by the U.S. Environmental Protection Agency (EPA), in accordance with labeled instructions;
 - maintain record of routine cleaning and sanitization of all facilities, containers, tools, contact surfaces and equipment and make records readily available to the Office upon request;
 - provide adequate safety lighting in all processing, distribution, storage and sale areas, as well as areas where equipment, tools, containers, or contact surfaces are cleaned;
 - provide sufficient space on the premises for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations;



- utilize appropriate environmental monitoring for temperature, ventilation, and humidity where cannabis or cannabis products are handled or stored so as to protect cannabis and cannabis products against their physical, chemical, and microbial contamination and deterioration;
- maintain records of pest management activities, including but not limited to the following information:
 - o a map of all traps, types, and coding/numbering system for the traps if applicable must be in place;
 - o a record of routine trap maintenance;
 - o a record of any evidence of animal or insect presence including body parts, hair, or feces in cannabis or cannabis product handling areas;
 - o properly remove and dispose of litter and waste so as to minimize the development of odor and minimize the potential for the waste attracting and harboring pests; and
 - store poisonous or toxic materials, insecticides, rodenticides, detergents, sanitizers, caustics, acids and other related cleaning compounds in separate areas from cannabis or cannabis products, in prominently and distinctly labeling containers, except that nothing herein precludes the convenient availability of detergents or sanitizers in areas where equipment, containers, and utensils are washed and sanitized;
- protect cannabis and cannabis products from all sources of contamination or adulteration, by
 establishing precautions to protect against allergen cross contact and any other potential
 contamination, by microorganisms or foreign substances, of cannabis or cannabis products, noncannabis components, contact surfaces, and packaging materials that are used in processing, among
 others
- Sanitary handling procedures. All licensees and their employees shall handle cannabis and cannabis products in a sanitary manner and comply with general sanitary requirements including but not limited to:
 - o maintaining adequate personal cleanliness;
 - washing and sanitizing hands thoroughly in an adequate hand-washing area before starting work, after each visit to a restroom, after handling contaminated material, eating, or at any other time when hands may have become soiled or contaminated;
 - o licensees shall ensure that all workers have access to hand washing and toilet facilities on the licensed premises and shall maintain such facilities in clean and sanitary condition, maintaining records of regular cleaning and sanitizing of such facilities.
 - hand-washing facilities on the licensed premises shall be furnished with running water at a suitable temperature and shall be located in the licensed premises in any processing or production areas and where good sanitary practices require employees to wash and sanitize their hands.
 - effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices shall be provided with the hand-washing facilities.
 - signage shall be displayed in toilet facilities to remind workers to wash and sanitize hands. Sanitary areas in this section must be marked in the licensee's site plan.
- equipment, products and materials necessary for cleaning and maintaining the facility shall be stored in a space separate from the storage of any cannabis or cannabis products or any cash.
- plumbing shall be of adequate size and design, and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the premises of the licensed entity.



- Plumbing shall properly convey sewage and liquid disposable waste from the premises of the licensed entity. There shall be no cross-connections between the potable and wastewater lines.
- hazardous waste handling, storage, and disposal must comply with New York State Department of Environmental Control standards.
- **8. Traceability.** A conditional processor shall assign a lot unique identifier, and batch number where applicable, which allows for complete traceability of all cannabis and cannabis products processed during a specific period of time and under similar conditions. All cannabis products must be identified and categorized in a processor's inventory tracking system, which includes but is not limited to information detailing the milligrams of total THC in the cannabis product, to ensure compliance with Article 20-c of the Tax Law and any other information required by the Office. Licensees must report data from their inventory tracking system to the Office upon request and pursuant to regulation and further guidance when available.
- **9. Sampling and Testing.** Adult-Use Conditional Processor licensees shall comply with all final product testing and sampling requirements, as set forth in regulations and guidance.
- 10. Requirements for Extraction. Only conditional processors approved to perform extraction activities can perform extraction activities under their Conditional Adult-Use Processor license. Unless otherwise approved in writing by the Board, a conditional processor authorized to perform extraction may only use the methods, equipment, solvents, gases, and mediums authorized under their existing hemp processing license when creating cannabis extracts and only in a manner exhibiting minimal potential for human health related toxicity. All extraction processes and activities must be conducted by employees adequately trained in the operation of the extraction equipment to be utilized, as well as in the emergency plan for incidents.

Licensees must be able to demonstrate control of all sources of ignition, and, if necessary, provide a spark- free environment where appropriate for the type of extraction method used. Licensees must ensure proper ventilation. Licensees must have ongoing equipment monitoring and maintain a record of regular maintenance of equipment based on equipment specifications and follow all applicable fire, safety and building codes, regulations, laws and guidance in the use and storage of solvents, including but not limited to, maximum quantities to be held onsite. Licensees must maintain evidence of the purity of any chemical solvents used, which must be at least 99% minimum purity, unless otherwise approved by the Board, and make any certificate of analysis or other documentation evidencing such purity readily available to the Office, upon request.

- **11. Acceptable Methods of Extraction.** Unless a conditional processor obtains prior written approval from the Board, extraction shall only be conducted using the following methods:
 - use of mechanical extraction methods, such as screens or presses, or heat, steam distillation, ice water and other methods without employing solvents or gases;
 - use of a professional grade, closed-loop CO2 gas extraction system that is of a supply equivalent to food or beverage grade of at least 99 percent purity;



- use of ethanol or alcohol-based extraction that must be of a grade that meets or exceeds specifications of official compendiums as defined in section 321 of Title 21 of the United States Code (USC);
- use of a volatile solvent or hydrocarbon extraction method, provided that the method:
 - o utilizes a commercial, professional grade closed-loop system designed to recover the solvent;
 - or utilizes the following permissible volatile solvent-based or hydrocarbon extraction substances, which must be accompanied by a Certificate of Analysis that establishes that the substances have a minimum purity level of 99 percent.
- In addition, for all proposed hydrocarbon extraction, a processor shall submit to the Office, prior to
 receiving approval to commence extraction operations at a processing facility and on the application
 for licensure if applicable, documentation which demonstrates the following additional requirements
 for all designated extraction equipment, rooms, or other areas where volatile solvents used for
 extraction are handled or stored:
 - A final certification letter from a licensed professional engineer or registered architect which certifies the completed installation of a professionally designed, commercially manufactured extraction system, that is compliant with all applicable state or local fire, safety or building codes;
 - a letter or equivalent document as determined by the Office from the municipal jurisdiction's fire marshal, or their designee, stating that a final inspection of the facility has been conducted and that the processor has demonstrated compliance with all applicable fire codes and/or regulations; and
 - o a current certificate of occupancy, or equivalent document, from the local building official that all permits for extraction related rooms or areas have been closed as applicable.
- **12. Permitted Adult-Use Cannabis Product Types.** A processor may produce the following types of cannabis products for retail sale:
 - topicals;
 - edibles (including single serving beverages, which may be sold in six packs);
 - vaporization cartridges or single-use pens;
 - concentrates;
 - tinctures;
 - capsules;
 - tablets:
 - cannabis flower products, including but not limited to whole flower, shake and pre-rolls; and
 - any other product type or form with prior written approval of the Office. In determining whether or not to approve a new cannabis product type, the Office may request written submission by the processor of the proposal, including but not limited to the proposed manufacturing process, methods of administration and any other factors which assess risk to public health and safety.
- **13. Prohibitions and Prohibited Cannabis Product Types.** A processor is prohibited from processing any cannabis products which:
 - contain liquor, wine, beer, cider or meet the definition of an alcoholic beverage as defined in section 3 of the Alcohol Beverage Control Law;



- contain tobacco or nicotine in the product;
- exceed the maximum total THC per serving and per package limits set forth by the Board;
- are attractive to individuals under twenty-one or violate the Board's packaging, marketing, and advertising prohibitions or guidance;
- contain synthetic cannabinoids, as defined in schedule I of section thirty-three hundred six of the public health law;
- require manufacture under sterile conditions;
- are considered a potentially hazardous food as defined by Section 14-1.31 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York;
- contain any non-phytocannabinoid ingredient that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. This prohibition shall not apply to products containing naturally occurring caffeine, such as coffee, tea, or chocolate;
- are manufactured by application of phytocannabinoid concentrate or extract to commercially
 available candy or snack food items without further processing of the product. Commercially
 available candy or snack food items may be used as ingredients in a cannabis product, provided that
 they are used in a way that renders them unrecognizable as the commercially available items, and the
 label, including the ingredient list, does not note that the final cannabis product contains the
 commercially available item; and
- are in the form of an injectable, inhaler, suppository, transdermal formulations, or any other disallowed form, as determined by the Board, including a form allowed solely for medical cannabis use, unless otherwise authorized by the Board.
- 14. Requirements for Adult-Use Cannabis Products. All cannabis products intended for oral ingestion including but not limited to edibles, capsules and tablets shall not exceed more than 10 milligrams (mg) of total THC per serving and 100 mg of total THC per package, unless otherwise approved in writing by the Board. Any approved cannabis product exceeding the 10 mg total THC per serving or 100 mg total THC per package may be subject to additional safeguards and oversight required by the Board to protect public health and safety, including but not limited to, additional packaging, labeling or consumer education requirements. Topical cannabis products and tinctures are not permitted to contain more than 1,000 milligrams of total THC unless approved by the Board in writing.
 - All cannabis products must:
 - accurately reflect testing results and not contain less than 85 percent or more than 115 percent of the concentration of total THC, CBD, or any other phytocannabinoid and terpene content as listed on the product label. Any cannabis product not meeting this requirement must be relabeled with the accurate phytocannabinoid and terpene content, unless otherwise permitted by the Board;
 - o be prepackaged, tested and labeled;
 - be shelf-stable, unless otherwise approved in regulation or by the Board, provided that nothing in this provision shall prohibit a processor from storing non-cannabis components or ingredients under refrigeration until use in product processing;
 - cannabis products may contain only excipients or ingredients which are appropriate for the cannabis product type manufactured and are, at a minimum, food grade or considered generally recognized as safe; and



o be homogeneous, with phytocannabinoid content evenly distributed throughout the cannabis product. This requirement shall not apply to cannabis flower products.

For Vaporization Cartridges and Single-Use Pens:

- Cannabis vaporization devices shall be a closed system with a pre-filled single-use cartridge that attaches to a rechargeable battery, or a single-use product.
- Electronic vaporization devices shall have internal or external temperature controls to prevent combustion and have a heating element made of inert material such as glass, ceramic or stainless steel and not plastic or rubber.
- Except for cannabis or botanically derived terpenes, excipients and ingredients must be pharmaceutical grade and appropriate for the cannabis product, unless otherwise approved by the Board.
- Cannabis Vaporization Cartridges and Single-Use Pens shall not include:
 - o synthetic terpenes;
 - o polyethylene glycol (PEG);
 - o vitamin E acetate;
 - o medium chain triglycerides (MCT oil);
 - o medicinal compounds;
 - o illegal or controlled substances;
 - o artificial food coloring;
 - o benzoic acid;
 - o diketones: and
 - o any other compound or ingredient as determined by the Board.
- Cannabis products cannot exceed more than 10% total terpenes.
- Licensees must maintain records of all cannabis or botanically derived terpenes used in the cannabis product with full information on the source of botanically derived terpenes used, and provide this information upon request.
- **15. Packaging, Labeling, Marketing, and Advertising.** Licensees must comply with all packaging, labeling, marketing, and advertising standards as set by the Board or in guidance from the Office.
- 16. Product Quality Plans and Batch Production Records. A processor shall implement and maintain a written product quality plan for each type of cannabis product processed at the licensed premises. Common plan types include a GMP Plan, Quality Assurance Plan, or Hazard Analysis and Critical Control Points (HACCP) Plan. The product quality plan shall address the risks and hazards associated with the premises and the manufacturing process that, if not properly mitigated, may cause the cannabis product to be adulterated or misbranded, or may cause the cannabis product to fail laboratory testing or quality assurance review. Each product quality plan must include a comprehensive assessment of the overall processing process, including all steps from component intake through transfer of product from the premises; evaluation of the potential risks associated with each processing step; and identification of preventive measures necessary to mitigate each potential risk identified, methods to evaluate the effectiveness of the preventive measure, and any action to take if a preventive measure was unsuccessful.

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Such plan shall also include written protocols for each unique formulation of cannabis product manufactured, and for each batch size, to ensure uniformity in finished batches and across all batches produced. Such protocols shall include the following:

- the name and intended phytocannabinoid content of the cannabis product to be manufactured;
- a complete list of all ingredients to be used and the weight or measure of each ingredient, which may include the ability to adjust the weight or measure of phytocannabinoid-containing ingredients in order to account for the variability of phytocannabinoid content across different batches;
- the identity and weight or measure of each ingredient that will be declared on the ingredients list of the cannabis product, if different than above;
- the expected yield of the finished manufactured cannabis product, based upon the quantity of ingredients or packaging to be used in the absence of any loss or error in actual production, and the maximum and minimum percentages of expected yield beyond which a deviation investigation of a batch will be necessary;
- a description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label;
- the expected number of packages and labels to be used, if the cannabis product will leave the manufacturing premises in final form;
- written instructions for each point, step, or stage in the processing process; and
- written instructions for any action to mitigate risks identified in the product quality plan.

All licensees must have written procedures in place to track and ensure no cross-contamination between cannabinoid hemp and adult-use cannabis processing activities and products at the licensees processing facility. Processors must be able to always distinguish between cannabinoid hemp products and adult-use cannabis products. All record keeping and tracking activities as described in sections 2 and8 must be applied to all cannabinoid hemp and adult-use cannabis processing. Upon inspection by the Office, licensees must be able to distinguish cannabinoid hemp extract and products from adult-use cannabis extract and products.

Licensees shall also maintain a written batch production record for every batch of a cannabis product manufactured, which shall include any batch specific remediation or relabeling. Records shall contain actual values and observations, as appropriate, during verification activities and be accurate and legible and be created concurrently with performance of the activity documented and include sufficient detail to provide a history of work performed, including the date each step was performed, and the signature or initials of the person performing the activity. The batch production record document shall also include, but not be limited to:

- lot number, or batch number as applicable, of the finished batch of cannabis product, and unique
 identification numbers or barcodes of all cannabis used in the batch as captured by the inventory
 tracking system of record;
- specific equipment and processing lines used in producing or remediating the batch;
- the identity and weight or measure of each component used;
- the actual yield and the percentage difference from expected yield at appropriate phases of manufacturing as identified in written protocols;



- the actual results obtained during any monitoring operation, if the product quality plan identifies any monitoring needed to ensure product safety at a specific manufacturing step;
- the date and time of when each step of the master manufacturing protocol was performed, and the initials of the person(s) performing each step;
- an actual or representative label or other identification of the label to be used for the cannabis product;
- the actual quantity of the packaging and labels used, and the difference from the expected number to be used, if the cannabis product will leave the manufacturing premises as a final cannabis product;
- documentation that quality control personnel reviewed the batch production record, including all
 required monitoring operations, test results for components, if applicable, and finished batches of
 cannabis product, and either approved and released, or rejected, the finished cannabis product,
 including any remediated, repackaged or relabeled cannabis product;
- documentation, at the time of performance, of any investigation identified in the product quality plan
 or written protocols, including investigations into deviations from the expected yield or package and
 label count.

Product quality plans and batch production records shall be readily available for employee reference and made readily available to the Board and Office upon request.

- **18. Inspections.** The licensee shall make available to the Office data required by this guidance to ensure compliance with the program standards set forth by the Board. The Office maintains the rights to inspect licensees' facilities where cannabis operations are taking place. Inspections may be on-site or through remote technology. Inspections may be announced or unannounced. Applicants will be provided with an inspection evaluation report, including, if necessary, a statement of findings and related timeline to make any corrective actions and submit a corrective action plan to the Office for review and approval.
- **19. Corrective Action Plan.** Any deficiencies identified by the inspection shall be documented in a statement of findings by the Office and require that the licensee submit a written plan of correction in a format acceptable to the Office within 15 calendar days of the issue date of the statement of findings. A plan of correction shall address all deficiencies or areas of noncompliance cited in the statement of findings and shall:
 - contain an assessment and analysis of the events and/or circumstances that led to the noncompliance;
 - contain a procedure addressing how the licensee intends to correct each area of noncompliance;
 - contain an explanation of how proposed corrective actions will be implemented and maintained to ensure noncompliance does not recur;
 - contain the proposed date by which each area of noncompliance shall be corrected;
 - any other information as directed by the Office.

Any inspection finding which the Office determines jeopardizes the immediate health, safety, or well-being of the public shall be deemed a critical deficiency and shall require immediate corrective action to remove the immediate risk. The licensee shall submit a preliminary corrective action plan to the Office within 24 hours of notification by the Office of the critical deficiency.



The Office has the authority to determine whether a corrective action plan needs modification, and if the licensee must modify the plan accordingly. Upon written approval of the Office, the licensee shall implement the plan of correction. Failure by the licensee to comply with these requirements may result in suspension, revocation, and or a civil penalty pursuant to the Cannabis Law or any applicable rule or regulation.

20. Employee and Training Requirements. Licensees shall not employ anyone under the age of eighteen years. Licensees must use due diligence to ensure that all employees possess the necessary education and training for the duties they will be assigned.

Licensees shall be required to develop and maintain an employee training manual. The employee training manual must include, at a minimum, employee guidelines and safety procedures; security protocols; training on standard operating procedures for all staff involved in extracting, processing, and/or manufacturing cannabis or cannabis products, which includes, but is not limited to: training that is specific to the duties assigned, and the safe operation of the equipment, machinery, solvents, gases and systems to be utilized; and training on the hazards presented by use of chemicals and solvents, as described in the safety data sheet for each. An up to date, readily available, complete employee training manual shall be made readily available at each licensed location. Copies of this manual must be maintained and be made available to the Board or Office upon request.

Licensees shall train employees and contractors in accordance with an employee training manual, which shall be made available in a language of fluency or primary language of all employees or contractors involved in the production and distribution of adult-use cannabis. The act, omission, or failure of an agent, officer, representative, or other person acting for or employed by a licensee, within the scope of his or her employment or position, shall in every case be deemed the act, omission, or failure of the licensee. Signed and dated documentation demonstrating each employee's attestation of completion of the training shall be made readily available to the Office upon request.

Licensees must maintain safety data sheets onsite, readily available to employees, and to the Office upon request, including information regarding emergency operations, notification to emergency personnel and shutdown procedures and information on how to access current laws, rules and regulations, and any guidance or policy documents issued by the Board or Office.

- **21. Security.** Licensees shall implement a security plan with sufficient security measures to deter diversion, theft or loss of cannabis and cannabis products or cash, prevent unauthorized entrance into areas containing cannabis or cannabis products, and to ensure the safety of the licensee's employees and the general public. In addition:
 - Cannabis and cannabis products shall be stored in a secure, locked safe, vault or other approved
 equipment or location within the licensed premises accessible to the minimum number of employees
 essential for efficient operation, to prevent diversion, theft or loss, and in such a manner, as to
 protect against physical, chemical and microbial contamination and deterioration of the cannabis and
 cannabis products.



- All facilities operated by a licensee where cannabis or cannabis products are stored or handled shall
 have a security and surveillance system to prevent and detect diversion, theft or loss utilizing
 commercial grade equipment.
- The license holder must maintain full-time security camera coverage of all parts of the interior and exterior of the licensed premises. Such equipment may be motion-activated after hours of business operation. Such equipment must comply with any current or future standards as determined by the Board.
- Employees, visitors, and other persons at licensed premises, including persons engaged in the transportation of cannabis or cannabis products, must be able to provide identification to the Office, or other authorized enforcement official upon request.
- Licensees shall notify the Office in a manner prescribed by the Office, of any breach of security or other incident set forth in this subdivision immediately and, in no instance, more than 24 hours following discovery of the security breach or incident.
- **22. Quarantine, Remediation and Recalls.** Licensees shall establish written policies and procedures to monitor and track all quality assurance concerns, and complaints from licensees and consumers, including, but not limited to, procedures for rapid notification to the licensees' supply and distribution chain to recall any lot of cannabis or cannabis product when directed by the Office, or as deemed necessary by the licensee. Such procedures must include notification to the Office with 24 hours of learning of a serious adverse event, quality assurance concern or initialing a recall.

Written procedures for recalling cannabis product, whether initiated by the licensee or mandated by the Office, shall include:

- identification of factors that necessitate recall and personnel responsible for implementing the recall procedures;
- notification protocols, including a mechanism to notify the Office within 24 hours of initiating a recall and to notify any licensee that supplied or received the recalled cannabis product;
- instructions to the general public and other licensees for the return or destruction of the recalled cannabis or cannabis products; and
- a requirement that all recalled products held by a licensee must be held in quarantine until the authorization of additional actions.

Licensees shall not sell or transfer cannabis or a cannabis product that has been placed on administrative hold by the Office, recalled, or ordered or otherwise required to be destroyed. Such cannabis or cannabis products shall be stored securely and separate and apart from other cannabis products while awaiting final disposition. All inventories, policies and procedures and other documents required by this section shall be maintained on the licensed premises and shall be made readily available to the Office upon request.

Licensees shall not sell or transfer cannabis product after the printed expiration date on the package.

23. Cannabis Waste Disposal. Licensees shall dispose of any cannabis or cannabis product that is outdated, damaged, deteriorated, contaminated, or otherwise deemed not appropriate for processing, distribution, or sale. This includes any plant-based cannabis waste created as a by-product of

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processing. All disposals must be conducted in compliance with all applicable state, and local laws, rules, regulations, and guidance. The disposal of cannabis shall mean that the cannabis has been rendered unrecoverable and beyond reclamation, by grinding and mixing the cannabis plant waste with other ground materials, so the resulting mixture is at least fifty percent non-cannabis waste by volume. The stalks, stems, fan leaves, root balls, and soil media of the cannabis plant shall not be required to be rendered unrecoverable beyond reclamation. Any other method used to render cannabis unrecoverable and beyond reclamation requires prior written approval of the Board.

Cannabis waste shall be maintained in a secured waste receptacle or secured area on the licensed premises until the time of disposal. All exterior cannabis waste receptacles located on the licensed premises shall be locked and secured to prevent unauthorized access. All cannabis waste and disposal shall be weighed, recorded and entered into the inventory tracking system prior to mixing and disposal. Cannabis waste may not be sold unless it is unrecoverable or beyond reclamation for use as a cannabis product.

Licensees shall maintain records of disposal for at least five years, and make available to the Board or Office for inspection, which shall include:

- the form (or type) of cannabis or cannabis product being disposed;
- the weight of the disposed cannabis material,
- the number of plants, or in the case of a cannabis product, the quantity of the cannabis product;
- the batch or lot number, as applicable, of the cannabis or cannabis product;
- the signatures of at least two of the licensee's employees who witnessed the disposal;
- the methods and destination/location of disposal, by waste type and weight, for each method of disposal; and
- any other information as determined by the Board.

For facilities generating more than a half ton of organic waste per week and within 25 miles of an organic recycling facility, the waste shall not be landfilled or combusted but must either be: 1) composted on-site or at an organic recycling facility; 2) used to produce energy through the process of anaerobic digestion; or 3) used as input by the licensee or a third party in the manufacture of other products, such as paper, packaging, or pet bedding.

24. Transportation. The transport of cannabis and cannabis products to an authorized licensee shall only be performed by a licensee or a licensee's authorized employee(s). Licensees shall ensure the safe and secure transport of any cannabis, or cannabis products, including the safety of those transporting cannabis. Cannabis and cannabis products shall be transported in a manner that will protect them against physical, chemical, and microbial contamination, and deterioration. All cannabis and cannabis products shall be transported in a secure manner in a fully enclosed vehicle, owned and operated by the licensee or hired and operated by the licensee from a trucking or transportation company. Cannabis and cannabis products being transported must be in a sealed package, which shall not be opened during transport.

Vehicles transporting cannabis or cannabis products shall be equipped pursuant to the Board's standards, including but not limited to:



- temperature controls designed, maintained, and equipped as necessary to prevent the cannabis and cannabis products from becoming unsafe during transportation;
- a secure lockbox or secure cargo area, which shall be used for the sanitary and secure transport of cannabis and cannabis products;
- an operational Global Positioning System (GPS) device, for identifying the geographic location of the vehicle, either permanently or temporarily affixed to the vehicle while the vehicle is in operation.

Vehicles shall bear no signs, markings, advertisements, or marketing that would either identify or indicate that the vehicle is used to transport cannabis or cannabis products. A licensee shall provide the Office, upon request, with information regarding any vehicles, including the vehicle's geographic location, make, model, color, vehicle identification number, license plate number, and vehicle registration. Transport of cannabis and cannabis products shall not be made through the use of an unmanned vehicle, such as a drone.

Any vehicle utilized for the purposes of transporting cannabis or cannabis products shall be considered an extension of the licensed premises and subject to inspection by the Office or authorized representative of the Office. Vehicles assigned for transportation may be stopped and inspected by the Office at any licensed location, or while on route during transportation.

- **25. Shipping manifests.** Prior to transporting any cannabis or cannabis products, a licensee shall generate a shipping manifest to be submitted to the licensee, permittee or other authorized party that will receive the cannabis, or cannabis product. The shipping manifest shall contain, at a minimum, the following information:
 - name, physical address, lot or batch number, and license or permit number of the originating licensee, permittee or other party authorized to receive cannabis or cannabis products;
 - name, physical address, and license number, if applicable, of the receiving party;
 - a certificate of analysis, except for those samples being transported to a permitted laboratory for
 - testing by a permitted sampling firm;
 - the unique identification numbers for all cannabis and cannabis products being transported;
 - the cannabis or cannabis product name, item category and weight or count of cannabis or cannabis products;
 - the estimated date and time of departure from the licensed premises;
 - the estimated date and time of arrival at each licensed premises;
 - the driver's license number of the employee transporting the cannabis or cannabis products;
 - the make, model, and license plate number of the vehicle used for transport; and
 - any other information as determined by the Office or Board.

The licensee receiving the delivery shall record acceptance or receipt of the delivery. The licensee shall record the receipt of delivery in the licensee's inventory tracking system.



Employees conducting the transport of cannabis or cannabis products shall possess a copy of the shipping manifest when transporting cannabis or cannabis products and shall produce it to the Office, the Office's authorized representative or law enforcement official upon request. A licensee shall not void, modify or change a shipping manifest or invoice after departing from the originating licensed premises. The licensee receiving and taking possession of cannabis or cannabis products shall ensure and verify that the cannabis or cannabis products being received and taken into possession for transport at the originating licensed premises are as described and accurately reflected in the shipping manifest. The licensee conducting the transport is responsible for any discrepancies between the shipping manifest and the cannabis and cannabis products in its possession during transport, and subject to any enforcement action related to such discrepancy. Shipping manifests and any invoices shall be made readily available to the Office, for inspection upon request, for a period of five years.

Employees of the licensee transporting cannabis and cannabis products shall:

- not make any unnecessary stops in between destinations;
- randomize transport times;
- have the ability to communicate with employees at the licensed entity at all times;
- only transport cannabis and cannabis products within the borders of New York State.

Where a transport is attempted and not completed and the cannabis or cannabis products remain in the possession of the employee conducting the transport, the employee shall return the cannabis or cannabis product to the licensed premises of the employee. The returned inventory may be restocked if the inventory is in a new, unopened condition and was handled in a manner that did not compromise the integrity of the cannabis or cannabis products. The cannabis or cannabis product inventory status must be updated in the licensee's inventory tracking system.

Only licensees, or employees thereof, may be in any vehicle as it is being used to transport cannabis or cannabis products.

26. Health and Safety Standards. Licensees shall comply with all applicable federal, state, and local laws and regulations related to worker training, safety, health, and pay. The licensee shall establish, maintain, and comply with a written alcohol-free, drug-free and smoke-free workplace policy.

Personal protective equipment must be assigned to employees involved in the processing of cannabis and cannabis products as needed and must be in good working order. If respirators are required, employees must be trained in their proper use and respirators must be serviced and tagged to manufacturer's specifications.

Licensees shall install informational signs that provide clear instructions for material handling, equipment operation, and general safety information for all operations. Licensee shall install warning signs in languages of fluency and the primary languages for the employees of the licensee in all areas of potential hazard.



Emergency signage must be posted in all work areas. At least one employee onsite must be trained in First Aid and CPR. Well stocked first aid kits must be readily available in all operational areas.

- **27. Labor Peace Agreement.** Within six months of licensure, the applicant must enter into a labor peace agreement with a bona-fide labor organization, and a signed copy of the labor peace agreement must be provided to the Office. Maintenance of such labor peace agreement is an ongoing material condition of licensure. For purposes of this requirement, a "bona fide labor organization" is defined as a labor union:
 - that represents employees in this state with regard to wages, hours and working conditions;
 - in which officers have been elected by secret ballot or otherwise in a manner consistent with federal law; and
 - that is free of domination or interference by any employer and has received no improper assistance or support from any employer.
- **28. Terms of Sale.** Licensees must sell cannabis product that are at prices indicative of its true value when sold without any other products or services. Licensees may not discriminate, directly or indirectly, in price, in discounts for time of payment or in discounts on quantity of merchandise sold between one retail dispensary and another retail dispensary purchasing cannabis bearing the same brand or trade name and of like age and quality.

Licensees authorized for distribution (distributors) must sell to any adult-use retail dispensary licensee willing to pay cash. The Office will maintain a list of all licensees delinquent in paying for cannabis products purchased on credit from distributors. Distributors cannot sell on credit to any retailer on the delinquent payment list. The Office reserves the right to investigate any sources of payment made by a dispensary.

Distributors may, but are not required to, allow licensees to pay on credit. All agreements to purchase cannabis on credit must be reported to the Office with the terms of payment and credit. Licensees that purchase cannabis products on credit have 90 days to pay for that purchase. Distributors must report licensees to the Office who are delinquent in payment. The Office reserves the right to invalidate agreements that it deems commercially unreasonable or where discriminatory pricing practices are suspected, and all licensees shall comply with future rules and regulations related to acceptable terms of credit.

For purposes of contesting and validating such claims in dispute before the Office,- licensees must keep dated records of all accounts payable and payments made and provide such records upon request by the Office within 48 hours, unless a period of time longer than 48 hours is permitted by the Office in writing.

29. Restrictions on Interests and Ownership. Licensees must ensure that all individuals and entities with an interest in their license are in compliance with the restrictions placed on such individuals and entities in the CAURD True Party of Interest guidance⁹. Licensees must comply with all requirements in that guidance including, but not limited to, requirements pertaining to ownership and contracting with

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landlords, financiers, financial institutions, or management services entities. A failure of any individual or entity with an interest in the licensee to comply with this guidance will be considered a failure of the licensee.

30. Undue Influence. To prevent suppliers from exerting inappropriate control over retail dispensaries, the Cannabis Law places restrictions on the ability of an entity in one tier from having an interest in an entity in another tier of the industry.

Cannabis cultivators, processors, and distributors, their true parties of interest, passive investors, and any management service providers cannot have any interest in a retail dispensary license. Applicants with an interest in such a business, no matter how small that interest is, will not be approved. A licensee who, themselves or through their True Parties of Interest, passive investors, or any management service providers, holds a prohibited interest risks their license being cancelled, suspended, or revoked or other enforcement actions being taken.

The Cannabis Law also prohibits licensees authorized to cultivate, process, or distribute cannabis from giving something of value to retail dispensaries to induce the retail dispensary to buy something from the licensee authorized to cultivate, process, or distribute cannabis. Generally speaking, the Office presumes that anything such licensee gives to a retail dispensary is meant to induce the retail dispensary to buy product including, but limited to: (1) gifts; (2) discounts, except not in excess of one per centum for payment on or before ten days from date of shipment of such cannabis; (3) customer loyalty programs; (4) loans of money; (5) premiums; (6) rebates; (7) free product of any kind, except as permitted in regulations or guidance; (8) treats or services; or (9) property.

Under no circumstances may a processor contract with a retail dispensary to perform any service, including but not limited to white labeling and branding agreements.

31. Availing. Availing is when a person who was not disclosed to the Office has an ownership or controlling interest in a licensed business. A licensee is responsible for violations committed by third parties who are availing the license.

Managers who oversee the business for the licensee are not availing the license. Availing occurs when the licensee turns control of the business over to an undisclosed party without any direction, supervision or oversight by the licensee, even if the undisclosed party does not profit from the use of the license. Availing may involve a failure to disclose an individual's interest in the business at the time the application is submitted to the Office or failure to disclose the transfer of an interest.

Evidence of availing includes:

- an agreement giving ownership to an undisclosed party;
- an undisclosed party receiving a percentage of the profits; and
- bank accounts, records and other licenses/permits in the undisclosed party's name.

An unauthorized entity change is a version of availing where the licensed entity stays the same, but the principals of the licensed entity, undisclosed to the Office, change. If a new person/entity is operating the



business, that is an availing. If the licensed entity is still in control but with different (unapproved) principal(s), that is an unauthorized corporate change.

To avoid an availing charge due to an authorized corporate change, be sure to obtain approval from the Office before making any ownership changes to your license.

- **32. Mentorship Program.** As a condition of licensure, Adult-Use Conditional Processors must participate in a social and economic equity mentorship program, as determined by the Office.
- **33.** Transition to Adult-Use Processor License. License holders must be compliant with all sections above to be eligible for license transition under the Conditional Adult-Use Processor law. The Board will evaluate compliance with all relevant laws, regulations, and guidance.

<u>Please Review and Sign on the Next Page and</u>
Upload the Signed Signature Page to Your Application on New York Business Express



The terms and conditions and guidance of the adult-use conditional processor license are binding on an Applicant for an adult-use conditional processor license and a person, partnership, or entity that receives an adult-use conditional processor license (Applicant). In addition, all Applicants are bound by current and future state laws, rules, regulations, terms and conditions, and guidance, and an Applicant is subject to the same authorizations and restrictions applied to any adult-use processor pursuant to section sixtynine of the Cannabis Law.

By signing below, the Applicant understands and agrees to the following:

"I understand that the statements made in this application will be accepted for all purposes as the equivalent of an Affidavit and that any false statements, including omissions, made herein, in addition to being the possible basis for a revocation of any approval given as a result of this application, may be punishable as a misdemeanor under the provisions of Section 210.45 of the Penal Law of the State of New York."

Print:			
Signed:			
Date:			